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Docket No. 55293-A/JPW/AJM/MVM

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Carlos Cordon-Cardo et al.
Serial No.: 09/329,917 Examiner: J. Souaya
Filed : June 10, 1999 Group Art Unit: 1634
For : MARKERS FOR PROSTATE CANCER
Date of Notice
of Allowance: July 23, 2002 Confirmation No.: 8767
Issue Fee Paid: October 23, 2002

1185 Avenue of the Americas
New York, New York 10036
February 28, 2003

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

**COMMUNICATION AND
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Applicants paid the issue fee for U.S. Serial No. 09/329,917 on October 23, 2002. In a petition being filed herewith, applicants petition that U.S. Serial No. 09/329,917 be withdrawn from issue under 37 C.F.R. §1.313(c)(2) in consideration of a Request for Continued Examination ("RCE") in compliance with 37 C.F.R. §1.114 filed herewith so that references not previously of record which are submitted with the accompanying Supplemental Information Disclosure Statement may be considered by the Patent Office.

Supplemental Information Disclosure Statement

Applicants are filing this Supplemental Information Disclosure Statement to supplement the Information Disclosure Statement filed on May 23, 2000, and the Supplemental Information Disclosure Statements filed on December 19, 2000 and October 10, 2002 in connection with the subject application.

Applicants: Carlos Cordon-Cardo et al.
Serial No.: 09/329,917
Filed: June 10, 1999
Page 2

In accordance with their duty of disclosure under 37 C.F.R. §1.56 and pursuant to 37 C.F.R. §1.97(b)(4), applicants direct the Examiner's attention to the references which are listed on the attached Form PTO-1449 (Exhibit A):

1. PCT International Application No. PCT/US98/14566, filed July 14, 1998, International Publication No. WO99/04238, published January 28, 1999;
2. PCT International Application No. PCT/US98/01922, filed January 29, 1998, International Publication No. WO98/33450, published August 6, 1998;
3. PCT International Application No. PCT/US94/03528, filed March 30, 1994, International Publication No. WO94/22478 A, published October 13, 1994 (Exhibit 1);
4. PCT International Application No. PCT/US98/26266, filed December 10, 1998, International Publication No. WO99/31140 A, published June 24, 1999 (Exhibit 2);
5. Aaltomaa, S. et al. (1999) "Prognostic Value and Expression of p21 (waf1/cip1) Protein in Prostate Cancer" *The Prostate*, 39(1):8-15 (Exhibit 3);
6. Agus, D.B. et al. (1999) "Response of Prostate Cancer to Anti-HER-2/neu Antibody in Androgen Dependent and - Independent Human Xenograft Models" *Cancer Research*, 59(1):4761-4764;
7. Arai, Y. et al. (1997) "C-erbB-2 Oncoprotein: A Potential

Applicants: Carlos Cordon-Cardo et al.
Serial No.: 09/329,917
Filed: June 10, 1999
Page 3

Biomarker of Advanced Prostate Cancer" *Prostate*, 30(3):195-201 (Exhibit 4);

8. Baretton, G.B. et al. (1999) "Proliferation- and Apoptosis-Associated Factors in Advanced Prostatic Carcinomas Before and After Androgen Deprivation Therapy: Prognostic Significance of p21/WAF1/CIP1 Expression" *British Journal of Cancer*, 80(3-4):546-555 (Exhibit 5);
9. Baselga, J. et al., (1998) "Recombinant Humanized Anti-HER2 Antibody (Herceptin TM) Enhances the Antitumor Activity of Paclitaxel and Doxorubicin Against HER2/neu Overexpressing Human Breast Cancer Xenografts" 58(13):2825-2831 (Exhibit 6);
10. Cariou S. et al. (1998) "Prognostic Implication of Expression of the Cell Cycle Inhibitor Protein P27", *Breast Cancer Research and Treatment*, 1-3(52):29-41 (Exhibit 7);
11. Cordon-Cardo Carlos, et al. (1998) "Distinct Altered Patterns of p27^{KIP1} Gene Expression in Benign Prostatic Hyperplasia and Prostatic Carcinoma" *J. Natl. Cancer Inst.* 90(17): 1284-1291;
12. Cote, R.J. et al. (1998) "Association of p27^{KIP1} Levels With Recurrence and Survival in Patients With Stage C Prostate Carcinoma" *J. Natl. Cancer Inst.* 90(12): 916-920;
13. Chen, Y. et al. (1998) "Increased Cell Growth and Tumorigenicity in Human Prostate LNCaP Cells by Overexpression to Cyclin D1" *Oncogene*, 16(15):1913-1920

Applicants: Carlos Cordon-Cardo et al.
Serial No.: 09/329,917
Filed: June 10, 1999
Page 4

(Exhibit 8);

14. Craft, N. et al., (1999) "A Mechanism for Hormone-Independent Prostate Cancer Through Modulation of Androgen Receptor Signaling by the HER-2/neu tyrosine Kinase" *Nature Medicine*, 5(3):280-285 (Exhibit 9);
15. Curnow, R.T. et al., (1997) "Clinical Experience With CD64-Directed Immunotherapy. An Overview" *Cancer Immunology And Immunotherapy*, 45(3-4):210-15 (Exhibit 10);
16. Database Biosis [Online] Biosciences Information Service, Philadelphia, PA, US (1999-03) Lee Tae Yoon et al., "Immunohistochemical Expression of p53 and MDM-2 Protein in Various Epithelial Carcinomas" Database Accession No. PREV1999900406745 (Exhibit 11);
17. DeMarzo, A.M. et al. (1998) "Prostate Stem Cell Compartments: Expression of the Cell Cycle Inhibitor p27kip1 in Normal, Hyperplastic, and Neoplastic Cells" *Amer. J. Path.* 153(3): 911-919;
18. Fernandez, P.L. et al. (1999) "Expression of p27/kip1 Is Down-regulated in Human Prostate Carcinoma Progression" *J. Path.* 187 (5): 563-566;
19. Gumbiner, L. et al. (1999) "Overexpression of Cyclin D1 Is Rare in Human Prostate Carcinoma" *Prostate*, 38(1):40-45 (Exhibit 12);
20. Guo, Y. et al. (1997) "Loss of the Cyclin-dependent Kinase

Applicants: Carlos Cordon-Cardo et al.
Serial No.: 09/329,917
Filed: June 10, 1999
Page 5

Inhibitor p27^{Kip1} Protein in Human Prostate Cancer Correlates with Tumor Grade¹" *Clin. Cancer Res.* 3:2269-2274;

21. Han, E. et al., (1998) "Cyclin D1 Expression in Human Prostate Carcinoma Cell Lines and Primary Tumors" *Prostate*, 35(2):95-101 (Exhibit 13);
22. James, N. et al., (1998) "Phase II Trial of the Bispecific Antibody MDX-H210 (Anti-Her2/Neu X Anti-CD64) Combined With GM-CSF In Patients With Advanced Prostate and Renal Cell Carcinomas That Express Her2/Neu" *British Journal of Cancer*, 78(Suppl 2):19 (Exhibit 14);
23. Koeneman, K.S. et al., (1999) "Osteomimetic Properties of Prostate Cancer Cells: A Hypothesis Supporting the Predilection of Prostate Cancer Metastasis and Growth in the Bone Environment" *Prostate*, 39:246-261 (Exhibit 15);
24. Lee, C.T. et al., (1999) "Overexpression of the Cyclin-Dependent Kinase Inhibitor P16 is Associated with Tumor Recurrence in Human Prostate Cancer" *Clinical Cancer Research, The American Association for Cancer Research, US*, 5(5):977-983;
25. Lloyd et al. (1999) "P27^{Kip1}: a Multifunctional Cyclin-dependent Kinase Inhibitor with Prognostic Significance in Human Cancers" *American J. Pathology* 154(2): 313-323;
26. McArthur, J.G. et al. (1999) "Cancer Gene Therapy with Novel Chimeric P27/p16 Tumor Suppressor Genes" *Proceed. Amer. Assoc. Cancer Res. Ann.* 40: 630;

Applicants: Carlos Cordon-Cardo et al.
Serial No.: 09/329,917
Filed: June 10, 1999
Page 6

27. Osman, I. et al. (1999) "Inactivation of the p53 Pathway in Prostate Cancer: Impact on Tumor Progression" *Clinical Cancer Research: An Official Journal of the American Association for Cancer Research*, 5(8):2082-2088;
28. Ross, J.S. et al., (1993) "Contribution of HER-2/neu Oncogene Expression to Tumor Grade and DNA Content Analysis in the Prediction of Prostatic Carcinoma Metastasis" *Cancer*, 72(10):3020-3028 (Exhibit 16);
29. Veltri, R. et al. (1994) "Quantitative nuclear morphometry, Markovian Texture Descriptors, and DNA content Captured on a CAS-200 Image Analysis Systems, Combined With PCNA and HER-2/neu Immunohistochemistry for Prediction of Prostate Cancer Progression" *Journal of Cellular Biochemistry*, 19:249-258 (Exhibit 17);
30. Yamasaki, I. et al. (1996) "Overexpression of MDM2 and p53 Protein is Infrequently but Significantly Associated With Progression of Human Prostatic Adenocarcinoma" *Oncology Reports*, 3(5):925-929 (Exhibit 18); and
31. Zhan, H. et al. (1992) "Expression of C-erb B-2/neu Proto-Oncogene in Human Prostatic Cancer Tissues and Cell Lines" *Molecular Carcinogenesis*, 5(4): 320-327 (Exhibit 19).

A Supplementary Partial European Search Report was issued on November 29, 2002 in connection with European Application No. EP 00938256.5, which is a related foreign counterpart of the subject application. A copy of the Supplementary Partial European Search Report is attached hereto as Exhibit B. Above-listed references

Applicants: Carlos Cordon-Cardo et al.
Serial No.: 09/329,917
Filed: June 10, 1999
Page 7

1-31 were cited in the Supplementary Partial European Search Report. References 6, 11-12, 20, 24 and 27 were submitted to and considered by the United States Patent and Trademark Office in an Information Disclosure Statement filed on May 23, 2000 in connection with the subject application. Reference 25 was submitted to and considered by the United States Patent and Trademark Office in a Supplemental Information Disclosure Statement filed on December 19, 2000 in connection with the subject application. References 1-2, 17-18 and 26 were submitted to and considered by the United States Patent and Trademark Office in a Supplemental Information Disclosure Statement filed on October 10, 2002 in connection with the subject application. Accordingly, copies of these references are not required to be provided to the United States Patent and Trademark Office, since they were previously submitted to and considered by the United States Patent and Trademark Office. References 3-5, 7-10, 13-16, 19, 21-23 and 28-31 are attached hereto as Exhibits 1-19, respectively.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

Applicants: Carlos Cordon-Cardo et al.
Serial No.: 09/329,917
Filed: June 10, 1999
Page 8

No fee, other than the \$375.00 RCE filing fee, included in the enclosed check for \$505.00, is deemed necessary in connection with the filing of this Communication and Supplemental Information Disclosure Statement. However, if an additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White
Registration No. 28,678
Alan J. Morrison
Registration No. 37,399
Attorneys for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

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